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S/N 10/523865

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kosaka	Examiner:	Gerido, Dwan A.
Serial No.:	10/523865	Group Art Unit:	1797
Filed:	February 7, 2005	Docket No.:	10921.0278USWO
Title:	PROTEIN ASSAY METHOD, INDICATOR FOR PROTEIN ASSAY, AND TEST PIECE FOR PROTEIN ASSAY		

CERTIFICATE UNDER 37 CFR 1.6:
The undersigned hereby certifies that this correspondence is being sent via facsimile to the United States Patent & Trademark Office, Commissioner for Patents (MAIL STOP: APPEAL BRIEF-PATENTS) on April 22, 2010.

By: _____
Name: Yuhgo Maruta

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S BRIEF ON APPEAL

Dear Sir:

This Brief is presented in support of the Notice of Appeal filed December 22, 2009, from the final rejection of Claims 1, 5, 7, 8, 12, 13 and 17-19 of the above-identified application, as set forth in the Office Action mailed June 23, 2009.

Please charge our Deposit Account No. 50-3478 in the amount of $540.00 to cover the required fee for filing this Brief.

I. REAL PARTY IN INTEREST

The application pending for this appeal has been assigned to ARKRAY, Inc., of Kyoto, Japan.

II. RELATED APPEALS AND INTERFERENCES

The Assignee, the Assignee's legal representatives, and the Appellant are unaware of any other appeals or interferences that will affect, be directly affected by or have a bearing on the Board's decision in this Appeal.

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III. STATUS OF CLAIMS

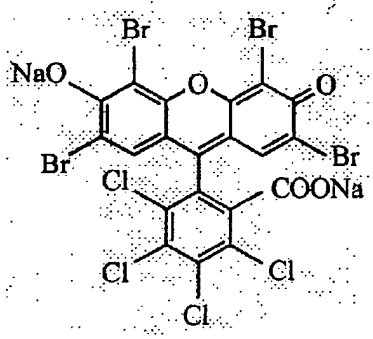
Claims 2-4, 6, 9-11 and 14-16 are canceled. Claims 1, 5, 7, 8, 12, 13 and 17-19 are pending. Claims 1, 5, 7, 8, 12, 13 and 17-19 are the subject of this Appeal. An Amendment was filed on April 20, 2010, under 37 C.F.R §41.33 to present rejected claims in better form for consideration on appeal. In particular, claim 8 was amended to correct an apparent editorial error. Appendix A attached herewith provides a copy of the claims in this Appeal. The claims in Appendix A track the claims that were included in the Amendment that was filed on April 20, 2010.

IV. STATUS OF AMENDMENTS

An Amendment and Response to the non-final Office Action was filed on February 13, 2009, under 37 C.F.R. §1.111. By way of the final Office Action mailed June 23, 2009, the Amendment and Response was considered, but deemed as not placing the application in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 is directed to a method for assaying albumin in urine by using a protein assay indicator (see page 3, lines 1-3 and Example 1 on page 7, line 23 to page 9, line 5 of the specification). The method for assaying albumin in urine of claim 1 requires a compound having a chemical structure expressed by one of the following Chemical Formulas (1)-1 and (1)-2 to be used as the protein assay indicator:



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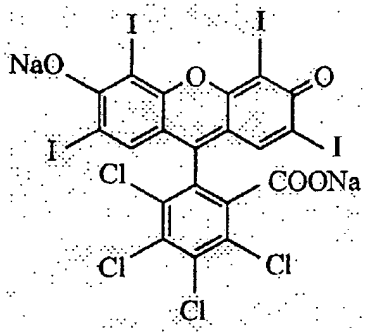
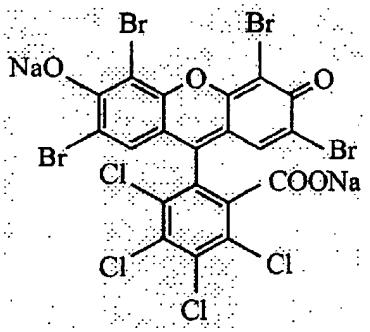


(1)-2

(see page 4, lines 1-5 of the specification).

The method of claim 1 can be used to evaluate the presence of albumin in urine (see Example 1 on page 7, line 23 to page 9, line 5 of the specification). Advantageously, according to the method of claim 1, unlike conventional protein detection methods using indicators such as tetrabromophenol blue (TBPB), albumin concentrations as low as 10 to 20 mg/dL can be detected in a urine sample (Id.).

Independent claim 8 is directed to a protein assay indicator for assaying albumin (see page 3, lines 1-3 and Example 1 on page 7, line 23 to page 9, line 5 of the specification). The protein indicator of claim 8 has a chemical structure expressed by one of the following Chemical Formulas (2)-1 and (2)-2:



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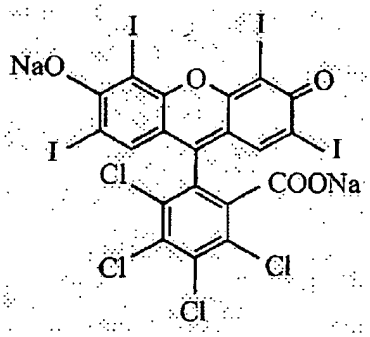
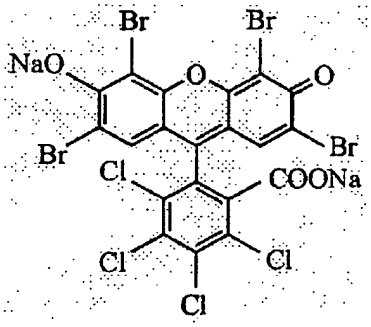


(2)-2

(see page 4, lines 1-5 of the specification).

The protein assay indicator of claim 8 can be used to evaluate the presence of albumin in urine (see Example 1 on page 7, line 23 to page 9, line 5 of the specification). Advantageously, the protein assay indicator in claim 8 has high sensitivity for albumin such that, unlike conventional protein assay detectors such as tetrabromophenol blue (TBPB), albumin concentrations as low as 10 to 20 mg/dL can be detected in a urine sample when the protein assay indicator of claim 8 is used to assay albumin in a urine sample (see Example 2 on pages 9-12 of the specification).

Independent claim 13 is directed to a test piece used for quantifying or semi-quantifying albumin in urine (see page 3, line 17 to page 6, line 4 and Example 2 at page 9, line 6 to page 12, line 9 of the specification). The test piece of claim 13 requires that a compound having a chemical structure expressed by one of the following Chemical Formulas (3)-1 and (3)-2 is used as a protein assay indicator:



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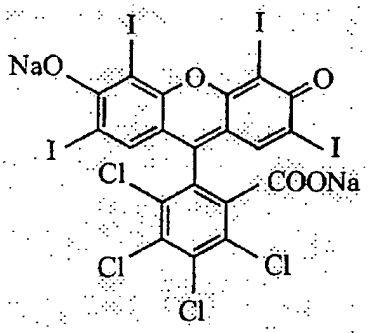


(3)-2

(see page 3, line 17 to page 6, line 4 and Example 2 at page 9, line 6 to page 12, line 9 of the specification).

The test piece of claim 13 can be used to evaluate the presence of albumin in urine (see Example 2 at page 9, line 6 to page 12, line 9 of the specification). Advantageously, the protein assay indicator of claim 13 has high sensitivity for detecting protein such that, unlike conventional test pieces that use protein assay detectors such as tetrabromophenol blue (TBPB), albumin concentrations as low as 10 to 20 mg/dL can be quantified or semi-quantified when the test piece of claim 13 is used to quantify or semi-quantify albumin in a urine sample (Id.).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following issues are raised in the final rejection:

1. Whether claims 1, 5, 6, 8, 12, 13 and 17 are obvious over Proffitt et al. (US Publication No. 2005/0106748) in view of Sujeeth (US Patent No. 5,772,696);
2. Whether claim 7 is obvious over Proffitt et al. (US Publication No. 2005/0106748) in view of Sujeeth (US Patent No. 5,772,696) and further in view of Lau (EP 0,361,244). For purposes of this appeal alone, Appellants are not contesting the relevance of Lau to claim 7 nor its suitability for combination with the remaining references. Claim 7 stands or falls with claim 1 from which claim 7 depends, and Lau will not be addressed further in this Brief; and
3. Whether claims 18 and 19 are obvious over Proffitt et al. (US Publication No. 2005/0106748) in view of Sujeeth (US Patent No. 5,772,696) and further in view of Bullard et al. (US 3,963,442). For purposes of this appeal alone, Appellants are not contesting the relevance of Bullard to claims 18 and 19 nor its suitability

for combination with the remaining references. Claims 18 and 19 stand or fall with claim 13 from which claims 18 and 19 depend, and Bullard will not be addressed further in this Brief.

VII. ARGUMENT

A. Claims 1 and 5 are patentable over Proffitt et al. (US Publication No. 2005/0106748) in view of Sujeeth (US Patent No. 5,772,696)

Claims 1 and 5 were rejected under 35 USC 103(a) as being unpatentable over Proffitt et al. (US Publication No. 2005/0106748) in view of Sujeeth (US Patent No. 5,772,696).

Appellant submits that when Proffitt and Sujeeth are each understood as a whole, the references do not teach that the Chemical Formulas (1)-1 and (1)-2 as recited in claim 1 can be used as a protein assay indicator for assaying albumin in urine, as required by claim 1.

Proffitt is directed to a method of applying an organic acid reagent having a low solubility in organic solvents or aqueous solvents, to a diagnostic test device (see Abstract of Proffitt). Proffitt indicates that the problems with organic reagents, which are typically applied to the absorbent material of diagnostic test devices, are that either they are soluble in aqueous solvents with no solubility or only limited solubility in organic solvents or are soluble in organic solvents with no solubility or only limited solubility in aqueous solvents (see paragraph [0007] of Proffitt). Proffitt explains that this means that these organic reagents have no transolubility or only limited transolubility in organic and aqueous solvents, and indicates that these organic acid reagents often do not dissolve well in organic solvents or aqueous solvents (Id.). To address such problems, Proffitt teaches mixing the organic acid reagent with an amine to enhance the transolubility (i.e., solubility in more than one of the following three types of solvents: aqueous solvents, non-aqueous solvents such as organic solvents and mixtures of aqueous and non-aqueous solvents of the organic acid reagent), and then applying the mixture to a diagnostic test device (see paragraphs [0025] and [0026] of Proffitt).

Proffitt provides pyrogallol red as a working example (see Examples 3-6 at paragraphs [0084] to [0100] of Proffitt). Proffitt indicates that pyrogallol red dye is a dye commonly used in diagnostic protein tests that is soluble in organic solvents such as methanol, but has no solubility or only limited solubility in aqueous solvents such as water or urine (see paragraph [0008] of

Proffitt). Proffitt explains that the challenge with pyrogallol red dye is applying the dye in a way so that it is soluble in an aqueous environment such as urine, but remains soluble in the organic solvent (Id.). In Example 3 of Proffitt, Proffitt provides data that appear to show different levels of solubility in an organic solvent and water mixtures when pyrogallol red dye is mixed with different amines (see paragraphs [0084] to [0087] of Proffitt). In Example 5, a test piece prepared using a mixture of pyrograllol red dye and an amine is used to detect different proteins, including albumin (see paragraphs [0092] to [0096] of Proffitt).

It is clear from the above that Proffitt does not provide any teaching that the Chemical Formulas (1)-1 and (1)-2 as recited in claim 1 can be used as a protein indicator for assaying albumin in urine. While Proffitt indicates that pyrogallol red dye may be used in their method for detecting protein, the reference in now way teaches or suggests that pyrogallol red dye is interchangeable with any of the other organic acid reagents disclosed by Proffitt for the detection of protein in urine. In fact, when Proffitt is understood as a whole, it is clear that Proffitt is focused on enhancing the solubility of an organic acid reagent by mixing the organic acid reagent with an amine, and merely teaches that various known organic acid reagents may be treated according to their methods for the known functions of the organic acid reagent.

The commercial product name for Chemical Formula (1)-1 of claim 1 is phloxine B and the commercial product name for Chemical Formula and (1)-2 of claim 1 is rose bengal (see Table 1 on page 9 of the specification). Phloxine B and rose bengal are mentioned in paragraph [0038] of Proffitt. Even accepting, arguendo, that phloxine B and rose bengal correspond to Chemical Formula (1)-1 and Chemical Formula (1)-2, respectively, the discussion at paragraph [0038] of the reference clearly teaches that phloxine B and rose bengal are merely a few of a large number of various dyes having various types of functions that can be used in their method. Nothing in the reference directs any particular attention to phloxine B and rose bengal. The reference likewise provides no reason to expect that phloxind B or rose bengal could be used for assaying albumin in urine and achieve the benefit of superior sensitivity of albumin detection in urine shown in the present specification.

Sujeeth does not remedy the deficiencies of Proffitt. Specifically, Sujeeth is directed to a method for purifying water soluble dyes, and in particular, quinoline, fluoran and xanthene dyes (col. 1, lines 9-12 of Sujeeth). The reference teaches that the dyes can be purified by adding a

salt to the dye solution to precipitate the dye as a dye salt, isolating the insoluble dye salt, and then converting the insoluble dye salt into a soluble dye solution by the addition of corresponding weak acid salts such as carbonate, bicarbonate, phosphate etc. (col. 3, line 51 to col. 4, line 17; col. 6, lines 57-61 of Sujeeth). Sujeeth provides a glossary of quinoline, fluoran and xanthene dyes that are in their insoluble and soluble form (col. 4, line 24 to col. 5, line 45 of Sujeeth). Thus, it is clear that Sujeeth is focused on the purification of certain dyes and fails to provide any guidance or experimental data showing that a compound having a chemical structure of Chemical Formulas (1)-1 or (1)-2 as recited in claim 1 could be used for assaying albumin in urine. Therefore, even when Proffitt and Sujeeth are combined, the references fail to teach or suggest the use of a compound having a chemical structure of Chemical Formulas (1)-1 or (1)-2 as a protein assay indicator for assaying albumin in urine as required by claim 1, or the accompanying benefits. Accordingly, claim 1 and its dependent claims are patentable over Proffitt and Sujeeth, taken alone or together.

B. Claims 8, 12, 13 and 17 are patentable over Proffitt et al. (US Publication No. 2005/0106748) in view of Sujeeth (US Patent No. 5,772,696)

Appellant submits that when Proffitt and Sujeeth are each understood as a whole, the combination of the references would not have yielded a predictable result of a protein assay indicator, as required by claims 8 and 13.

Proffitt is focused on providing a method of enhancing the transolubility of organic acid reagents in general, and is silent as to the particular functions of the large number of organic acid reagents listed in paragraph [0038] other than pyrogallol red dye.

Moreover, Proffitt teaches that in order to enhance the transolubility of the organic acid reagent, the organic acid reagent is reacted with an amine to form a salt complex (see paragraph [0025] of Proffitt). Proffitt specifically indicates that for the detection of proteins, the salt complex that is formed by the reaction between an organic acid reagent and an amine binds to the protein (see paragraph [0050] of Proffitt). The reference further explains that the salt complex may have functions such as a color change upon binding to protein that can be preserved or enhanced due to an attraction to the liphilic or hydrophilic portion of the protein, and the amine that is used to form the salt complex may impart these solubility and compatibility properties to the organic acid reagent (Id.).

Thus, it is clear that Proffitt teaches that for the detection of proteins, the amine salt that is formed between an organic acid reagent and an amine is the protein assay indicator, and that the amine may be responsible for the detection properties. In contrast, claim 8 requires the protein assay indicator to be have a chemical structure expressed by one of Chemical Formulas (2)-1 and (2)-2. Claim 13 requires the protein assay indicator used in the test piece to have a chemical structure expressed by one of Chemical Formulas (3)-1 and (3)-2. Chemical Formulas (2)-1 and (2)-2 of claim 8 are not amine salts. Chemical Formulas (3)-1 and (3)-2 of claim 13 also are not amine salts. The reference fails to provide any basis to show that there would have been a reasonable expectation success in achieving a protein assay indicator having a chemical structure expressed by one of Chemical Formulas (2)-1 and (2)-2 as required by claim 8 or Chemical Formulas (3)-1 and (3)-2 as required by claim 13, and achieve superior sensitivity in the detection of albumin in urine.

Sujeeth does not remedy the deficiencies of Proffitt. Specifically, Sujeeth is directed to a method for purifying water soluble dyes, and in particular, quinoline, fluoran and xanthene dyes (col. 1, lines 9-12 of Sujeeth). The reference teaches that the dyes can be purified by adding a salt to the dye solution to precipitate the dye as a dye salt, isolating the insoluble dye salt, and then converting the insoluble dye salt into a soluble dye solution by the addition of corresponding weak acid salts such as carbonate, bicarbonate, phosphate etc. (col. 3, line 51 to col. 4, line 17; col. 6, lines 57-61 of Sujeeth). Sujeeth provides a glossary of quinoline, fluoran and xanthene dyes that are in their insoluble and soluble form (col. 4, line 24 to col. 5, line 45 of Sujeeth). However, the reference fails to provide any basis to show that there would have been a reasonable expectation success in achieving a protein assay indicator having a chemical structure expressed by one of Chemical Formulas (2)-1 and (2)-2 as required by claim 8 or Chemical Formulas (3)-1 and (3)-2 as required by claim 13, and achieve superior sensitivity in the detection of albumin in urine. Accordingly, claims 8 and 13 and their dependent claims are patentable over Proffitt and Sujeeth, taken alone or together.

C. Claim 7 is Allowable with Claim 1

Claim 7 is included in the rejection for obviousness over Proffitt and Sujeeth and further in view of Lau. As noted above in Section VI, for purpose of this appeal only, Appellants are not contesting the relevance of Lau to claim 7 nor its suitability for combination with Proffitt and

Sujeeth. Claim 7 is allowable for at least the reasons discussed above for its independent claim 1.

D. Claims 18 and 19 are Allowable with Claim 13

Claims 18 and 19 are included in the rejection for obviousness over Proffitt and Sujeeth and further in view of Bullard et al. As noted above in Section VI, for purpose of this appeal only, Appellants are not contesting the relevance of Bullard et al. to claims 18 and 19 nor its suitability for combination with Proffitt and Sujeeth. Claims 18 and 19 are allowable for at least the reasons discussed above for its independent claim 13.

VIII. CONCLUSION

Appellant submits that the rejections of claims 1, 5, 7, 8, 12, 13 and 17-19 are untenable for the reasons set forth above and should be reversed.

Please charge any additional fees or credit any overpayment to Hamre, Schumann, Mueller & Larson Deposit Account No. 50-3478.

Respectfully submitted,

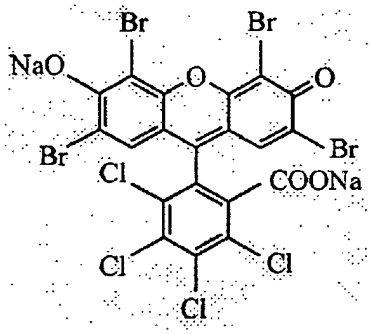
Hamre, Schumann, Mueller & Larson, P.C.
P.O. Box 2902-0902
Minneapolis, MN 55402
Phone: 612-455-3800

Date: April 22, 2010

By _____
Name: Douglas P. Mueller
Reg. No. 30,300

APPENDIX A - PENDING CLAIMS

1. (rejected) A method for assaying albumin in urine by using a protein assay indicator, wherein a compound having a chemical structure expressed by one of the following Chemical Formulas (1)-1 and (1)-2 is used as the protein assay indicator:



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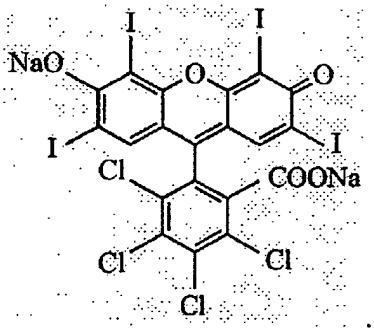


(1)-2

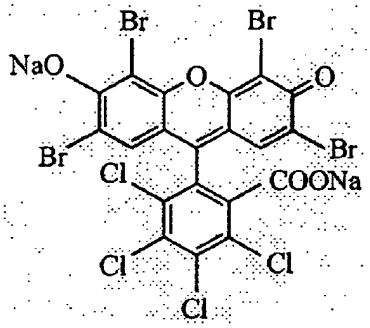
2.-4. (canceled)

5. (rejected) The method according to claim 1, wherein the protein indicator is from colorless to light orange in color when no protein is present at a pH equal to or below the pKa of said protein indicator, but is from red to purple in color when a protein is present.

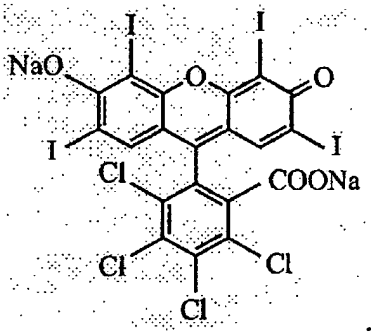
6. (canceled)

7. (rejected) The method according to claim 1, wherein albumin concentration is measured for an albumin-containing sample whose albumin concentration is between 10 and 20 mg/dL.

8. (rejected) A protein assay indicator for assaying albumin in urine, said indicator having a chemical structure expressed by one of the following Chemical Formulas (2)-1 and (2)-2:



(2)-1

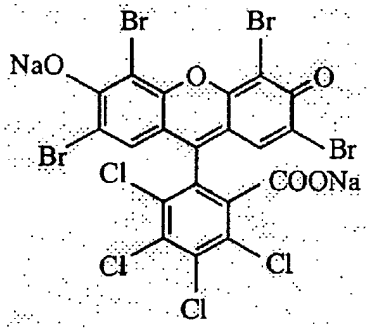


(2)-2

9.-11. (canceled)

12. (rejected) The protein assay indicator according to claim 8, wherein the indicator is from colorless to light orange in color when no protein is present at a pH equal to or below the pKa, but is from red to purple in color when a protein is present.

13. (rejected) A test piece used for quantifying or semi-quantifying albumin in urine, wherein a compound having a chemical structure expressed by one of the following Chemical Formulas (3)-1 and (3)-2 is used as a protein assay indicator:



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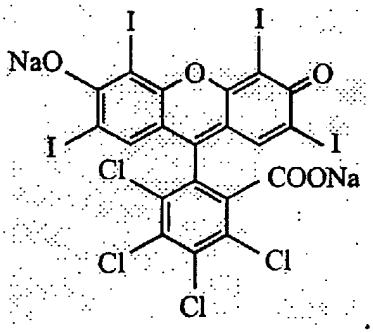

(3)-2

14.-16. (canceled)

17. (rejected) The test piece according to claim 13, wherein the protein indicator is from colorless to light orange in color when no protein is present at a pH equal to or below the pKa of said protein indicator, but is from red to purple in color when a protein is present.

18. (rejected) The test piece according to claim 13, further containing a sensitizer for increasing the coloration sensitivity with respect to the protein.

19. (rejected) The test piece according to claim 18, containing one of polyethylene glycol and polypropylene glycol as the sensitizer.

APPENDIX B - EVIDENCE

Not applicable

APPENDIX C - RELATED PROCEEDINGS

Not applicable